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| APPLICATION NO.  | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
|--|---------------|----------------------|---------------------|------------------|--|
| 09/931,557   | 08/16/2001    | Walter Bruce Markham |                     | 4254             |  |
| 75   | 90 02/05/2004 |                      | EXAMINER            |                  |  |
| Veracel, Inc.  |               |                      | WALLENHORS          | ST, MAUREEN      |  |
| 59 Adelaide Street, 4th Floor<br>Toronto, M5C1K9<br>CANADA |               |                      | ART UNIT            | PAPER NUMBER     |  |
|  |               |                      | 1743                |                  |  |

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |  | Application No.  | Applicant(s)  | V       |  |  |  |
|--|--|--|---|---------|--|--|--|
| Office Action Summary  |  | 09/931,557   | MARKHAM ET AL.  |         |  |  |  |
|  |  | Examiner   | Art Unit  |         |  |  |  |
|  |  | Maureen M. Wallenhorst   | 1743  |         |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |  |   |         |  |  |  |
| THE - Exte after - If the - If NC - Failu Any  | ORTENED STATUTORY PERIOD FOR REPL' MAILING DATE OF THIS COMMUNICATION.  nsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication.  period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period of the polymer of the provision of the pr | 36(a). In no event, however, may a rep<br>y within the statutory minimum of thirty (<br>vill apply and will expire SIX (6) MONTH<br>cause the application to become ABAF | ly be timely filed<br>30) days will be considered timely.<br>HS from the mailing date of this communic<br>NDONED (35 U.S.C. § 133). | cation. |  |  |  |
| Status   | •  |  |   |         |  |  |  |
| 1)   | Responsive to communication(s) filed on  | _·   |   |         |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) This action is non-final.  |  |  |   |         |  |  |  |
| 3)[  | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |  |   |         |  |  |  |
|  | closed in accordance with the practice under E   | x parte Quayle, 1935 C.D.  | 11, 453 O.G. 213.   |         |  |  |  |
| Disposit   | ion of Claims  |  |   |         |  |  |  |
| 4)⊠  | Claim(s) 1-88 is/are pending in the application  |  |   |         |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |  |  |   |         |  |  |  |
| •  | Claim(s) is/are allowed.   |  |   |         |  |  |  |
| -  | 6) Claim(s) is/are rejected.   |  |   |         |  |  |  |
|  | Claim(s) is/are objected to.   | election requirement   |   |         |  |  |  |
| 8) Claim(s) <u>1-88</u> are subject to restriction and/or election requirement.  |  |  |   |         |  |  |  |
| Applicat   | ion Papers   |  |   |         |  |  |  |
| ,  | The specification is objected to by the Examine  |  |   |         |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.   |  |  |   |         |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |  |   |         |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. |  |  |   |         |  |  |  |
| 11)[   | The path of declaration is objected to by the E.   | xammer. Note the attached  | Office Action of format 10-10   | J.L     |  |  |  |
| Priority   | under 35 U.S.C. § 119  |  |   |         |  |  |  |
|  | Acknowledgment is made of a claim for foreign  |  | 119(a)-(d) or (f).  |         |  |  |  |
| 1. Certified copies of the priority documents have been received.  |  |  |   |         |  |  |  |
| <ul><li>2. Certified copies of the priority documents have been received in Application No</li><li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li></ul>                     |  |  |   |         |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  |  |  |   |         |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |  |  |   |         |  |  |  |
|  |  |  |   |         |  |  |  |
|  |  |  |   |         |  |  |  |
| Attachme   | nt(s)  |  |   |         |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date.  |  |  |   |         |  |  |  |
| 3) 🔲 Info  | rmation Disclosure Statement(s) (PTO-1449 or PTO/SB/08   | 5) Notice of Inf   | formal Patent Application (PTO-152)   | l       |  |  |  |
| Pap  | er No(s)/Mail Date   | 6)   |   |         |  |  |  |

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## RESTRICTION

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-71, drawn to a method of isolating a monolayer of cells, classified in class 436, subclass 177.
  - II. Claims 73-78, drawn to an apparatus for holding and mixing specimens, classified in class 422, subclass 102.
  - III. Claims 72 and 79-85, drawn to a method and apparatus for collecting cells in a container having an upstream and a downstream section separated by a choke, classified in class 422, subclass 101.
  - IV. Claims 86-88, drawn to a slide assembly for microscopic examination of cells, classified in class 435, subclass 288.3.
- 2. The inventions are distinct, each from the other because:
- Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus since the method of Group I does not require a vessel having projections therein to be performed.
- 4. Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as

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claimed can be practiced by another materially different apparatus since the method of Group I does not require a container having an upstream and downstream end separated by a choke to be performed.

- Inventions I and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process since the apparatus of Group IV does not require the removal of unwanted materials from a cell sample in a cuvette for use. The apparatus of Group IV could be used to examine cells from a blood or urine sample that is applied directly to the slide assembly from the body without any preliminary separation/filtration that is required by the method of Group I.
- 6. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The invention of Group II operates to hold and mix a cell sample by having projections within an interior space of a container. The invention of Group III operates to collect and filter cells from a sample by a container having therein a filter, and an upstream and downstream section separated by a choke. The invention of Group II does not require a filter and an upstream and downstream section separated by a choke, whereas the invention of Group III does not require a container having projections therein.

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7. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The invention of Group II operates to hold and mix a cell sample by having projections within an interior space of a container. The invention of Group IV operates to form a monolayer of cells on a slide for microscopic examination by the provision of a slide having an adhesive coating thereon. The invention of Group II does not require a slide having an adhesive coating thereon, whereas the invention of Group IV does not require a container having projections therein.

- 8. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The invention of Group III operates to collect and filter cells from a sample by a container having a filter therein, and an upstream and downstream section separated by a choke. The invention of Group IV operates to form a monolayer of cells on a slide for microscopic examination by the provision of a slide having an adhesive coating thereon. The invention of Group III does not require a slide having an adhesive coating thereon, whereas the invention of Group IV does not require a container having a filter therein, and an upstream and downstream section separated by a choke.
- 9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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- Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the 12.

examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-

1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00

PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst Primary Examiner Art Unit 1743

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February 3, 2004

maurier m. Wallerhorst MAUREEN M. WALLENHORST PRIMARY EXAMINER

GROUP # 1700